PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 29312-0207	**FOR FURTHER ACTION** See Form PCT/IPEA/416	
International application No. PCT/CA2004/000604	International filing date *(day/month/year)* 23.02.2004	Priority date *(day/month/year)* 23.04.2003
International Patent Classification (IPC) or national classification and IPC G07C9/00, A61M5/178		
Applicant VASOGEN IRELAND LIMITED et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 7 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☒ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23.02.2005	22.07.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Ceccarelli, D Telephone No. +49 89 2399-2653

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CA2004/000604

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-16 as originally filed

Claims, Numbers

1-79 as originally filed

Drawings, Sheets

1/18-18/18 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☒ the claims, Nos. 1-48
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CA2004/000604

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	12-15,32-37,41-46,48-52,58,59,66-71,77-79
	No:	Claims	1-11,16-31,38-40,47,53-57,60-65,72-76
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-79
Industrial applicability (IA)	Yes:	Claims	1-79
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item I
Basis of the report

The amended claims under Article 19(1) PCT offend against the requirements of Article 19(2) PCT, since their subject-matter goes beyond the disclosure in the international application as filed. Therefore said amended claims have not been considered for carrying out the examination according to Article 33(1) PCT and the examined claims are those of the originally filed application.

1. Amended claim 1, allegedly based on original claim 20, in particular features a second identification means having data associated with an entity, the entity being associated with the dispensing means.
   There is no basis in the application as filed for the combination of a delivery system as claimed in original claim 20 and the defined second identification means.
   In the original application, the only possible basis for the now claimed second identification means is one of the following disclosures:
   1) the combination of claims 54 and 62;
   2) lines 8-20, page 5, together with lines 8-16, page 6;
   3) lines 13-21, page 11.
   In all of these disclosures, however, **the second identification means are only shown in combination with valve means and valve control means,** which are not part of amended claim 1.
   The subject-matter of amended claim 1 has therefore no basis in the original disclosure.

2. Also for the wording of claims 3 and 10-48 when taken alone, no corresponding disclosure can be found in the original application and the Applicant has not indicated any.

Re Item V
Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Independent claims 1, 20 and 54 are not novel (Article 33(2) PCT) over the disclosure of document US 6 519 569 (D1), for example.
Said document shows a delivery system comprising dispensing means (10, figure 1), which can be in the form of syringe means (lines 44-47, column 2), onboard dispensing control means (control panel 22, figure 1, see also lines 3-5, column 5), which, in case pumping device 10 is a cassette pump or a peristaltic pump (see lines 56-60, column 4), comprise valve means, first identification means (label 66, figure 1) and permission control means which can be in the form of valve control means (lines 25-31, column 8, see also figures 3A and 3B).

2. Dependent claims 2-11, 16-19, 21-31, 38-40, 47, 52-53, 55-57, 60-65 and 72-76 are also not novel (Article 33(2) PCT) over the disclosure of document D1.
See in particular column 5, line 67 to column 6, line 22 for the identity of the "associated entity", the "dispensing recipient" and the storage means for the "second identity data".

3. Claims 12-15, 32-37, 41-46, 48-52, 58, 59, 66-71 and 77-79 are not considered to involve an inventive step (Article 33(3) PCT) when document D1 is considered as closest prior art.
Said document D1 teaches how to provide a safe way of administering a medicament to a patient intended to receive it, by electronically verifying the match between the medicament and the patient.
The mechanical means claimed in said claims 12-15, 32-37, 41-46, 48-52, 58, 59, 66-71 and 77-79, and needed for particular embodiments of said teaching are considered to be within the competence of the skilled man, and have already been applied in the medical field, as shown in documents US 4 415 802, WO 02/15957, US 4 685 314 and US 2003/055685 (see in particular respective figures).

4. It is to be noted that the disclosures of documents US 5 272 318, US 4 415 802, WO 02/15957 and US 4 685 314 are all concerned with the idea of preventing unintended delivery of a medicament to a wrong patient by matching two identity data carriers on the medicament container/delivery device and the patient respectively (see abstracts).
Therefore their disclosures deprive the subject-matter of all claims at least from

inventiveness (Article 33(3) PCT).

Re Item VII

Certain defects in the international application

The claims do not contain **reference signs** to the figures (Rule 6.2(b) PCT). The independent claims are not in the two-part form (Rule 6.3(b) PCT).
Documents US 6 519 569, US 5 272 318, US 4 415 802, WO 02/15957 and US 4 685 314 have not been cited in the description (Rule 5.1(a)(ii) PCT).

Re Item VIII

Certain observations on the international application

The presence of three independent claims (1, 20 and 54) almost completely overlapping in scope in the present application does not allow to clearly delimit the subject-matter for which protection is sought.
As a result a lack of clarity and conciseness of the claims as a whole arises (Article 6 PCT).

CLAIMS:

1. A delivery system, comprising:

dispensing means having an outlet for delivering one or more materials;

dispensing control means for controlling the passage of the material through the outlet;

first identification means having first identity data associated with the dispensing means or the material carried thereby, the first identification operable in a data recording mode or a data emitting mode;

second identification means having second identity data associated with an entity, the entity being associated with the dispensing means, the second identification means operable in a data recording mode or a data emitting mode; and

permission control means operable to establish a predetermined condition of the dispensing control means when a corresponding predetermined relationship is established between the first identity data and the second identity data.

2. A system as defined in claim 1 wherein the entity is a dispensing recipient, a medical professional or clinician.

3. A system as defined in claim 2 wherein the entity is a dispensing recipient and the second identity data is embedded in, carried by or emitted by an article carried externally or internally by the recipient.

4. A system as defined in claim 1, claim 2 or claim 3 wherein the dispensing control means includes an access means for controlling access to the outlet.

5. A system as defined in claim 4 wherein the access means includes valve means, or outlet blockage member or both.

6. A system as defined in claim 5 wherein the valve means or outlet blockage member is operable between an open position and a closed position, and is normally closed.

7. A system as defined in claim 5 or claim 6 wherein the access means is a valve means comprising a variable aperture valve member, a controlled valve member, a proportional valve member or a combination thereof.

8. A system as defined in any of claims 4 to 7 wherein the valve means is a pulse width modulated on-off valve.

9. A system as defined in claim 5 wherein the access means includes an outlet blockage member comprising a lockable cap member..

10. A system as defined in claim 1 wherein the first or second identification means, or both, are arranged to retain the first identity data or the second identity data in electronic, graphical, mechanical or nuclear form.

11. A system as defined in claim 10 wherein the first or second identification means, or both, are operable to convey the first identity data or the second identity data on a carrier wave.

12. A system as defined in claim 11 wherein the carrier wave includes radio frequency waves, microwaves or waves or signals of other frequencies or frequency ranges.

13. A system as defined in claim 11 or claim 12 wherein the first identity or the second identity data is resident on the carrier wave by frequency modulation, amplitude modulation, wave superposition or a combination thereof.

14. A system as defined in any of the preceding claims wherein the permission control means includes comparison means for comparing the first identity data with the second identity data.

15. A system as defined in claim 14 wherein the comparison means is operable to receive and decode an RFID signal from the dispensing means, the entity or both.

16. A system as defined any of the preceding claims wherein the first identification means includes a biometric sensor, an optical character reader, a magnetic strip reader, an RFID reader or a combination thereof.

17. A system as defined in any of claims 1 to15 wherein the first identification means includes a signal emitter and/or receiver to emit and/or receive signals in the visible or invisible frequency spectrums.

18. A system as defined in any of claims 3 to 17 wherein the article includes a band or ring to be worn on a leg, arm or neck of the recipient.

19. A system as defined in claim 18 wherein the article includes an identification chip such as an RFID tag associated with the second identity data.

20. A system as defined in any of claims 4 to 19 wherein the access means is a valve means and the first identification means includes valve identity data to identify the valve means; and the second identification means includes article identity data to identify an article associated with the valve means; the comparison means being operable to open the outlet when there is a match between the valve identity data and the article data.

21. A system as defined in claim 20 wherein the comparison means is operable to close the valve means to block access to the outlet when there is a mismatch between the valve identity data and the article identity data.

22. A system as defined in claim 20 or claim 21 wherein the comparison means is resident in an intermediate controller module which is operable within signal receiving range of the valve means, the onboard blockage member and the article.

23. A system as defined in claim 22 wherein the comparison means is integrally formed within the dispensing means.

24. A system as defined in any of claims 5 to 23 wherein the access means is a valve means which includes a valve element powered by a power supply portion.

25. A system as defined in claim 24 wherein the power supply portion includes a power source residing in the power supply portion, a conductive path to an external power source, or an inductive power generating module which is responsive to externally applied radiation, or a combination thereof.

26. A system as defined in claim 25 wherein the power supply portion is integrally formed with the dispensing means.

27. A system as defined in claim 25 or claim 26 wherein the power supply portion is an inductive power generating module, and the externally applied radiation is within the microwave or radio wave frequency ranges.

28. A system as defined in any of claims 1 to 8 wherein the permission control means includes a key portion associated with the second identity data.

29. A system as defined in claim 28 wherein the key portion is located on an article carried externally or internally by the entity.

30. A system as defined in claim 28 or claim 29 wherein the key portion is operable to engage a complementary key receiving portion to establish the predetermined condition.

31. A system as defined in claim 30 wherein the key receiving portion is located on the dispensing means.

32. A system as defined in claim 30 or claim 31 wherein the key-receiving portion includes a key receiving-passage.

33. A system as defined in any of claims 28 to 32 wherein the permission means is operable to expose the key portion to the key-receiving portion.

34. A system as defined in claim 33 wherein the key portion is movable between a concealed position and an exposed position.

35. A system as defined in any of claims 28 to 34 wherein the key portion is stationary relative to the article and the permission means further comprises a key shroud which is operable between a key-concealing condition and a key-revealing condition.

36. A system as defined in any of claims 3 to 35 wherein the first and second identification means includes complementary first and second key formations located on, in or near the valve means and the associated article respectively.

37. A system as defined in claim 36 wherein the first key formation is located on the dispensing means and the second key formation is located on the associated article so that the dispensing means and associated article may positioned so that the first and second

key formations be brought into complementary engagement with one another to establish the predetermined relationship.

38. A system as defined in any of the preceding claims wherein the dispensing means includes syringe means, IV bottle, powder and/or atomized fluid and/or gas inhalant dispenser, implant delivery dispenser, ventilator, syringe pump, intubation tube, or a gastrointestinal feeding tube or a plurality and/or a combination thereof.

39. A system as defined in claim 38 wherein the dispensing means is a syringe having a barrel portion, a chamber portion and plunger portion, the plunger portion positioned in the barrel portion, an onboard dispensing control means including lock means for locking the position of the plunger portion.

40. A system as defined in claim 39 wherein the syringe has a valve portion downstream of and separable from the chamber portion, the permission control means including a comparison means for comparing the first identity data with the second identity data, the comparison means being located in the valve portion.

41. A system as defined in claim 39 or claim 40 wherein the onboard dispensing control means includes an onboard valve means located in the barrel portion or downstream thereof.

42. A system as defined in claim 39, claim 40 or claim 41 wherein the onboard dispensing control means includes an onboard blockage member located in the barrel portion or downstream thereof.

43. A system as defined in claim 39 wherein the outlet is downstream of a plunger-containing chamber portion, the valve means further comprising a valve housing attachable with and/or separable from the outlet.

44. A system as defined in any of the preceding claims wherein the entity is dispensing recipient selected from a medical patient, an experimental subject and/or a candidate for a treatment or procedure.

45. A system as defined in claim 44 wherein the dispensing recipient is mammalian.

46. A system as defined in claim 45 wherein the dispensing recipient is a human being.

47. A system as defined in any of the preceding claims wherein the material has beneficial properties to enhance life, to promote health, to cure and/or treat a disease, condition or ailment, to monitor and/or indicate a bodily function or a combination thereof.

48. A system as defined in any of the preceding claims wherein the material is useful for IV therapy, implantation, stem cell therapy, oncology therapy, blood transfusion and/or organ transplantation.